

REMARKS

An Office Action was issued September 2, 2004 informing the Applicants that the claims section of the Amendment filed August 11, 2004 was incorrect, because certain claims that were both amended and withdrawn had not been properly identified as such. This paper corrects that error in the claims section of the Amendment filed August 11, 2004 by indicating that claims 7, 12, 18, and 19 are “withdrawn-currently amended,” as required by the Office Action. Otherwise, the claims section of this paper is the same as the claims section of the Amendment filed August 11, 2004.

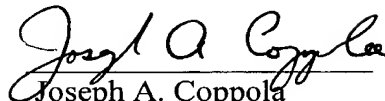
The time for responding to the Office Action was set for October 2, 2004. Therefore, it is believed that this paper is timely. If this is in error, please treat this paper as containing a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this paper and charge any corresponding fees to Kenyon & Kenyon’s Deposit Account No. 11-0600.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon’s Deposit Account No. 11-0600 for the Petition fee and

any other fees required to effect this Conditional Petition.

Respectfully submitted,

BY:


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Reg. No. 38,413

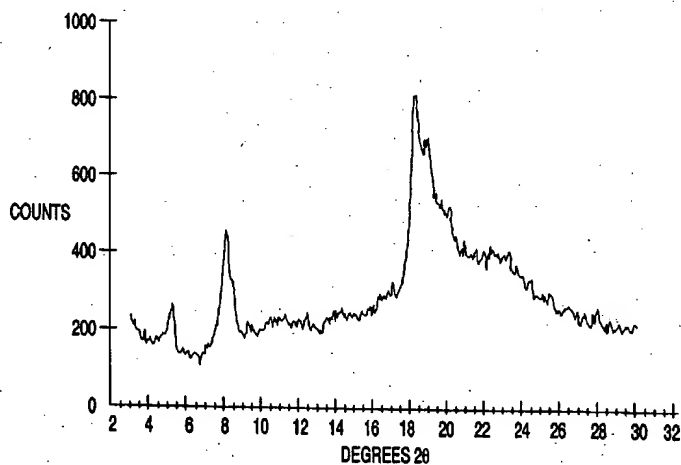
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Date: September 20, 2004

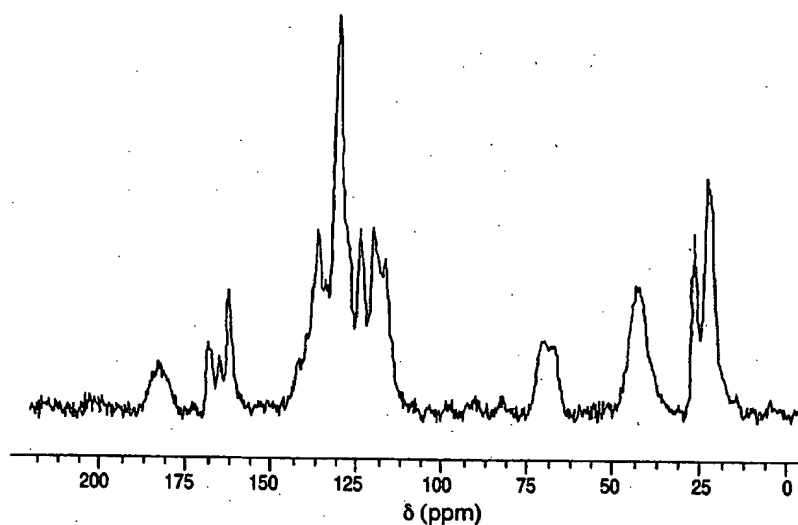
CLAIM AMENDMENTS

This listing of claims will replace all prior versions and listings of claims in the application:

1. (currently amended) Atorvastatin calcium Form V or hydrate thereof produced by a process comprising the steps of
 - a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution
 - b) contacting the atorvastatin salt solution with a calcium salt, and
 - c) isolating crystalline atorvastatin calcium Form V or hydrate thereof.
2. (currently amended) ~~The atorvastatin~~ Atorvastatin calcium Form V or hydrate thereof ~~of claim 1~~ having an X-ray powder diffractogram substantially as depicted ~~in Figure 1~~ follows



3. (currently amended) ~~A crystalline form of atorvastatin~~ Atorvastatin calcium Form V and hydrates thereof characterized by X-ray powder diffraction peaks at about 5.5 and 8.3 degrees at 2θ and a broad peak at about 18-23 \pm 0.2 degrees 2θ .
4. (currently amended) ~~The atorvastatin~~ Atorvastatin calcium Form V or hydrate thereof of claim 1 having a solid state ^{13}C NMR spectrum substantially as depicted in Figure 2 follows



5. (currently amended) ~~A crystalline form of atorvastatin~~ Atorvastatin calcium Form V and hydrates thereof characterized by solid state ^{13}C NMR signals at about 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.
6. (currently amended) Atorvastatin calcium Form V of claim 1 containing up to about 9 moles of water per mole of atorvastatin calcium.

7. (withdrawn - currently amended) A process for preparing ~~a crystalline form of~~ atorvastatin calcium Form V and hydrates thereof of either of claims 3 or 5, comprising the steps of
- a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution
 - b) contacting the atorvastatin salt solution with a calcium salt, and
 - c) isolating ~~the crystalline form of~~ atorvastatin calcium Form V or ~~hydrate~~ hydrates thereof.
8. (withdrawn) The process of claim 7 wherein the salt of atorvastatin is a metal salt of atorvastatin.
9. (withdrawn) The process of claim 8 wherein the metal salt of atorvastatin is a sodium salt of atorvastatin.
10. (withdrawn) The process of claim 7 wherein the calcium salt is calcium acetate.
11. (withdrawn) The process of claim 7 wherein the calcium salt is dissolved in a solvent and the atorvastatin salt solution is contacted with the calcium salt by adding the calcium salt solution to the atorvastatin salt solution.

12. (withdrawn - currently amended) A process for preparing a ~~crystalline form of~~ atorvastatin calcium Form V or ~~hydrate~~ hydrates thereof of either of claims 3 or 5, comprising the steps of
- a) dissolving atorvastatin calcium in a solvent selected from the group consisting of tetrahydrofuran and hydroxylic solvents to form an atorvastatin calcium salt solution,
 - b) adding water to the atorvastatin calcium salt solution, and
 - c) isolating ~~the crystalline form of~~ atorvastatin calcium Form V or hydrate hydrates thereof.
13. (withdrawn) The process of claim 12 wherein the solvent is methanol.
14. (withdrawn) The process of claim 12 wherein the solvent is ethanol.
15. (withdrawn) The process of claim 12 wherein the solvent is tetrahydrofuran.
16. (currently amended) A pharmaceutical composition comprising a therapeutic amount of atorvastatin Form V or hydrates thereof of claim 1, 3, or 5.
17. (previously presented) Atorvastatin calcium form V and hydrates thereof characterized by x-ray powder diffraction peaks at about 5.5 and 8.3 +/- 0.2 degrees 2 θ and ¹³C NMR signals at about 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

18. (withdrawn - currently amended) A method of making atorvastatin calcium ~~form~~ Form V of claim 2 or 4 and hydrates thereof comprising the steps of:

a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution

b) contacting the atorvastatin salt solution with a calcium salt, and

c) isolating atorvastatin calcium Form V or hydrate thereof.

19. (withdrawn - currently amended) A method of making atorvastatin calcium Form V or hydrate thereof of either of claims 2 or 4, comprising the steps of:

a) dissolving atorvastatin calcium in a solvent selected from the group consisting of tetrahydrofuran and hydroxylic solvents to form an atorvastatin calcium salt solution,

b) adding water to the atorvastatin calcium salt solution, and

c) isolating the atorvastatin calcium Form V or hydrate thereof.